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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/978,217	11/25/97	BENZ	C 02307E-07111

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EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/978,217	Benz, C.C. et al.
Examiner	**Group Art Unit**
Anne Holleran	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-81* is/are pending in the applicat

Of the above, claim(s) *28-70, 72-78, 80, and 81* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-27, 71, and 79* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. The previous communication, a letter stating that the reply to the restriction requirement was not fully responsive (Paper No. 10, mailed Sep. 01, 1999) was sent in error and has been vacated.

Election/Restriction

2. Applicant's election, with traverse, of Group I, claims 1-15, 71 and 79 in Paper No. 9, filed June 28, 1999 is acknowledged. Upon further consideration of the restriction requirement, Groups I and II have been rejoined and claims 1-27, 71 and 79 will be examined.

Upon further consideration, groups III and IV are rejoined to each other. However, Applicant's arguments for rejoining the other groups have been carefully considered and not found persuasive. Applicant argues that the restriction requirement between groups VI, VII, VIII, IX and X is illegal because of the requirement that some of the claims that are to be examined in part. Applicant asserts that the imposed restriction requirement is illegal because the claims as currently recited may not be presented in their original form in subsequent prosecution. This argument is not found persuasive because nothing in the restriction requirement of the claims in the instant case precludes Applicant from presenting the withdrawn claims, as originally recited, in a subsequent application. If Applicant pursues subsequent Applications, any restriction

requirement for those claims will be considered during the prosecution of the subsequent application.

Applicant's attention is also drawn to the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 which set forth the possibility for rejoining method claims to product claims. Method claims *limited to the scope of the allowable product claims* will be rejoined and examined at the time the product claims are indicated as being allowable.

Applicant further asserts that the restriction requirement is unnecessary because examining all of the claims would not impose an undue burden on the Examiner. However, the restriction requirement as set forth establishes, prima facie, that examination of all of the claims would impose an undue burden on the Examiner because the claims are drawn to three separate products, nucleotides, polypeptides and antibodies that are art recognized to be patentably separate products capable of separate use and manufacture and which are classified differently in U.S. Patent shoes.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Notes

4. The recitation "has" or "having" appears in many of the claims and is associated with clauses limiting the structure of the claimed polynucleotides. A list is provided to indicate how each recitation is interpreted.

In claim 1, the recitation "has an amino acid sequence as set forth in SEQ ID NO: 7..." is interpreted as closed language, i.e. "consisting of an amino acid sequence...".

In claim 2, the recitation "having an amino acid sequence.." is interpreted as open language, i.e. "comprising an amino acid sequence ...".

In claim 3, the recitation "has a nucleotide sequence ..." is interpreted as open language, i.e. "comprising an amino acid sequence ...".

In claim 7, the recitation "has an amino acid sequence ..." is interpreted as closed language, i.e. "consisting of an amino acid sequence...".

In claim 10, the recitation "has an amino acid sequence ..." is interpreted as open language, i.e. "comprising an amino acid sequence...".

In claim 16, the recitation "having an amino acid sequence..." is interpreted as closed language, i.e. "consisting of an amino acid sequence...".

In claim 17, the recitation "having an amino acid sequence..." is interpreted as closed language, i.e. "consisting of an amino acid sequence...".

In claim 18, the recitation, "has a nucleotide sequence..." is interpreted as open language, i.e. "comprising a nucleotide sequence ...".

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 16-27 of this application. Claims 16-27 are drawn to murine ESX polynucleotides which are not disclosed in provisional application 60/031,540. Figure 5 of provisional application does not contain a polypeptide or polynucleotide sequence. SEQ ID NOS: 15 and 16 are not disclosed in provisional application 60/031,540. None of the claims in provisional application 60/031,504 are drawn to murine polynucleotides encoding murine polypeptides. For purposes of comparison with the prior art, the filing date of the instant application (Nov. 25, 1997) will be used for claims 16-27.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9, and 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation "an ESX transcription factor variable region polypeptide". The specification does not define what is an ESX transcription factor

variable region polypeptide. For examination purposes, the phrase will be interpreted to mean a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO: 7.

Claim 2 is vague and indefinite in its reference to SEQ ID NO:3 as an amino acid sequence. Both the CRF and the paper copy of the sequence listing indicate that SEQ ID NO: 3 is a nucleotide sequence. For examination purposes, claim 2 will be interpreted to be drawn to a polynucleotide comprising a nucleotide sequence encoding at least about 5 contiguous amino acids of a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO: 7, wherein said nucleic acid sequence comprises the nucleic acid sequence as set forth in SEQ ID NO: 3; or alternatively claim 2 will be interpreted to be drawn to a polynucleotide comprising a nucleotide sequence encoding at least about 5 contiguous amino acids of a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO: 7, wherein said nucleic acid encodes an ESX transcription factor comprising an amino acid sequence as set forth in SEQ ID NO: 2.

Claim 15 is vague and indefinite because the recitation "said polypeptide" in line 4 could either refer to the "human ESX transcription factor polypeptide" or to the polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 1. For examination purposes, the recitation "said polypeptide" will be interpreted to mean "human ESX transcription factor polypeptide".

Claim 27 is vague and indefinite because the recitation "said polypeptide" in line 4 could either refer to the "murine ESX transcription factor polypeptide" or to the "polypeptide shown as MESX in Figure 5".

Claim 19 is vague and indefinite because SEQ ID NOS: 16 and 17 are amino acid sequences but are referenced in the claim as if they were polynucleotide sequences of polynucleotide primer sequences.

Claims 5 and 20 are vague and indefinite in the recitation "hybridizes ... under stringent conditions" which is used as a limitation on the structure of a claimed polynucleotide sequence. It is not possible to assess the metes and bounds of the claimed polynucleotides because a specific set of hybridization conditions has not been recited in the claims.

Claims 16 and 27 are vague and indefinite in the their reference to Figure 5. Claims must be complete in themselves (MPEP 2173.05) and reference within a claim to a specific figure or table is permitted only in exceptional circumstances. Applicant is advised to amend the claims to recite an amino acid sequence identified by SEQ ID NO. For purposes of examination, because the current Figure 5 contains the amino acid sequence set forth in SEQ ID NO: 16, claims 16-27 will be interpreted to be drawn to polynucleotides encoding the amino acid sequence of SEQ ID NO: 16.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

X. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids comprising a polynucleotide sequence as set forth in SEQ

ID NO: 3 or comprising a polynucleotide sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for the full scope of nucleic acids comprising polynucleotides encoding any 5 contiguous amino acids derived from the amino acid sequence of SEQ ID NO: 7 or from an amino acid sequence of SEQ ID NO: 7 containing conservative amino acid substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

Claim 1 is drawn to polynucleotides which encode a genus of polypeptides. The ability of one of skill in the art to know how use the claimed invention is tied to the usefulness of the encoded polypeptides which is in turn tied to the biological function of the encoded polypeptides. Claim 1 is drawn to a genus of nucleic acids which comprise nucleotide sequences encoding at least about 5 contiguous amino acids of an ESX transcription factor variable region polypeptide, the sequence of which is set forth in SEQ ID NO: 7. The recitation of claim 1 allows for conservative substitutions of the amino acid sequence of SEQ ID NO: 7. Thus, the species of nucleic acids encompassed by this claim may be as small as 15 nucleotides in length or may be as

large as that of a gene sequence that happens to comprise a set of 15 nucleotides that encode for any 5 contiguous amino acids of SEQ ID NO: 7, wherein SEQ ID NO: 7 may contain conservative amino acid substitutions.

The disclosure of the specification teaches that SEQ ID NO: 7 is an 84 amino acid fragment of SEQ ID NO: 2 (amino acids 104-187 of SEQ ID NO: 2), an amino acid sequence of a polypeptide that is asserted to be an ETS polypeptide. The prior art teaches that ETS polypeptides are oncogenes that are structurally related to each other in that all of the proteins that have been identified contain within the amino acid sequence an ETS-domain which is a stretch of 85 amino acids capable of direct sequence-specific DNA-binding (Janknecht, R. et al., Biochim. Biophys. Acta, 1155: 346-356, 1993; IDS ref. "AG"). Thus, the assertion that SEQ ID NO: 2 is the amino acid sequence of an ETS polypeptide is based on sequence searches of amino acid sequence databases that shows that SEQ ID NO: 2 contains within its sequence a region that has a high sequence similarity to the ETS DNA binding domain of other proteins identified as ETS proteins.

The biological function of or uniqueness of SEQ ID NO: 7 as a region within the amino acid sequence of SEQ ID NO: 2 is not taught or asserted by the disclosure of the specification. Thus, the biological function of proteins that may contain regions that are similar to that of SEQ ID NO: 7 is not possible to discern from the teachings of the disclosure of the specification. Furthermore, the polynucleotides encoding polypeptide fragments that are encompassed by claim 1 have no asserted utility and one of skill in the art would not know how to use them other than

as probes for nucleotides encoding proteins which may contain similar small regions. However, the information provided by a search using such probes would not be useful until further, undue experimentation or further inventing was done by one of skill in the art, which would be required to discern the biological function of the polypeptides encoded by the newly found polynucleotides. Therefore, given the broad scope of the claimed invention which includes polynucleotides encoding polypeptides that are yet to be discovered; given the lack of teachings in the disclosure of the specification concerning the function or uniqueness of the region of SEQ ID NO: 2 from which the 5 amino acids are chosen; and given the fact that the 5 contiguous amino acids may be chosen from a sequence containing any number of conservative amino acid substitutions, one of skill in the art would not know how to use the nucleic acids encoding these proteins or protein fragments without undue experimentation and with a reasonable expectation of success.

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The disclosure of the specification teaches a working example of how the unique cDNA sequence encoding for an ESX transcription factor was discovered (Example 1); EST (expressed sequence tag) databases were searched using an 8 amino acid fragment as a query sequence. The specification teaches that the 8 amino acid fragment was known, at the time the invention was

made, to be the sequence of a motif that is unique to ETS DNA-binding domains of proteins previously identified as belonging to the ETS family of oncogenes.

Claim 1 is drawn to polynucleotides comprising nucleotide sequences encoding 5 contiguous amino acids from a fragment of SEQ ID NO: 2; the fragment may contain conservative amino acid substitutions. As discussed above, no biological function is ascribed to the fragment of SEQ ID NO: 2 from which the sequence of 5 amino acids is derived, nor does the specification assert that this region is unique to a particular class of proteins. Thus, nucleotides comprising polynucleotide sequences encoding polypeptides containing 5 contiguous amino acids derived from a fragment of SEQ ID NO: 2 which may have conservative amino acid substitutions, reads on yet to be discovered polynucleotide sequences encoding polypeptides with yet to be discovered functions. Thus, one of skill in the art would not find that Applicant was in possession of the invention as claimed.

7. Claims 1, 2, 5, 7, 15, 16, 17 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 5, 7, 15, 16, 17 and 27 are drawn to nucleic acids encoding polypeptides with open language. The scope of the claimed nucleic acids is such that claims 1, 2, 5, 7, 15, 16, 17 and 27 read on the genes encoding for polypeptides. Genes encompass sequences such as

cDNA, genomic sequences and sequences that also contain the promoter and regulatory regions necessary for gene functioning. The specification teaches cDNA sequences and genomic sequences containing non-coding regions but does not disclose full gene sequences comprising promoters and regulatory regions. Thus, one of skill in the art would not understand that the applicant was in possession of the full scope of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-16, 19-27 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,789,200 (Kola et al, published Aug. 4, 1998; filed Nov. 15, 1996; effective U.S. filing date Oct. 31, 1996).

Claim 1 and dependent claims 4-9 are drawn to nucleic acid molecules comprising a nucleotide sequence encoding at least 5 contiguous amino acids of a polypeptide sequence of SEQ ID NO: 7 or of said polypeptide sequence with conservative substitutions. Claims 4-9 further limit the nucleic acid of claim 1 by limiting the nucleic acids to nucleotide sequences that may be amplified from a genomic library using primer pairs SEQ ID NO: 13 and SEQ ID NO: 14 (claim 4), nucleotide sequences that hybridizes to a clone of a human ESX gene (claim 5), nucleotide sequences that further comprises a vector (claim 6), nucleic acids comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 7 (claim 7), nucleic acids comprising nucleotide sequences which have a less than 0.5 or 0.2 smallest sum probability when compared to SEQ ID NO: 6 using a BLASTN algorithm using default parameters (claims 8 and 9, respectively).

Claim 10 and dependent claims 11-14 are drawn to nucleic acid molecules comprising a label and a nucleotide sequence encoding a polypeptide comprising an amino acid sequence as set forth in SEQ ID NO: 12 or comprising an amino acid sequence as set forth in SEQ ID NO: 12 with conservative substitutions. Claims 11-13 further limit the nucleic acid of claim 10 by limiting the nucleic acids to those that are free of dideoxynucleotides (claim 11), that are single stranded (claim 12), that have the sense orientation (claim 13), or that are labeled with a radionuclide.

Claim 15 is drawn to nucleic acid molecules comprising a polynucleotide sequence encoding a polypeptide comprising at least 8 contiguous amino acid sequence encoded by a nucleic acid as set forth in SEQ ID NO: 1.

Claim 16 and dependent claims 19-26 are drawn to nucleic acids comprising a nucleotide sequence encoding at least about 10 contiguous amino acids from a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO: 16. Claims 19-26 further limit the nucleic acid of claim 16 by limiting the nucleic acids to nucleotide sequences that may be amplified from a genomic library using primer pairs (for examination purposes, SEQ ID NO: 13 and SEQ ID NO: 14 (claim 19), nucleotide sequences that hybridizes to a clone of a murine ESX gene (claim 20), nucleotide sequences that further comprises a vector (claim 21), to labeled nucleic acids (claim 22), to labeled nucleic acids free of dideoxynucleotides (claim 23), to labeled nucleic acids that are single stranded (claim 24), to labeled nucleic acids that are sense strands (claim 25) and to labeled nucleic acids that are radiolabeled (claim 26).

Claim 27 is drawn to an isolated nucleic acid encoding a polypeptide comprising at least 8 contiguous amino acids from the polypeptide sequence shown in SEQ ID NO: 16.

Claim 71 is drawn to a transfected cell comprising a heterologous gene encoding an ESX transcription factor.

U.S. Patent 5,789,200 discloses a nucleotide sequence that is the same as that of claim 1 (see Figure 1A and SEQ ID NO: 1; nucleotides 424-675). U.S. Patent 5,789,200 discloses amino acid sequence SEQ ID NO: 2 which comprises the amino acid sequence of SEQ ID NO: 7 of the instant application (see amino acids 104-187 of SEQ ID NO: 2 (Figure 1B-1)); comprises a polypepide consisting of a sequence of at least 8 or 10 contiguous amino acids of SEQ ID NO: 16

(see sequence alignment) and thus, discloses a nucleic acid comprising a polynucleotide sequence that is the same as those of claims 1, 7, 16 and 27.

Hybridization of a nucleic acid with both of SEQ ID NOS: 13 and 14 is an inherent property of a nucleic acid of claims 4 and 19. SEQ ID NO: 1 of U.S. Patent 5,789,200 provides a 100 % identity match with either of SEQ ID NOS: 13 or 14. Thus, U.S. Patent 5,789,200 teaches a polynucleotide sequence which is the same as the sequence of nucleic acids of claims 4 and 19 (see sequence alignments).

SEQ ID NO: 3 of the instant application is an example of a polynucleotide sequence of a clone of a human ESX gene, and SEQ ID NO: 15 of the instant application is an example of a polynucleotide of a clone of a murine ESX gene. SEQ ID NO: 3 of the instant application has a high degree of sequence similarity with the polynucleotide sequence of SEQ ID NO: 1 of U.S. Patent 5,789,200 (see sequence alignment). SEQ ID NO: 15 comprises sequence segments that have a high degree of sequence similarity with the polynucleotide of SEQ ID NO: 1 of U.S. Patent 5,789,200 (see sequence alignment). Thus, U.S. Patent 5,789,200 teaches a polynucleotide sequence that is capable of hybridizing to a clone of human ESX or murine ESX and is nucleic acid that is the same as those of claims 5 and 20.

U.S. Patent 5,789,200 teaches polynucleotides further comprising a vector (column 17, line 26 - column 22, line 67). A BLASTN analysis of SEQ ID NO: 6 demonstrates (see enclosed alignment) that SEQ ID NO: 6 has a less than 0.2 smallest sum probability when compared with

SEQ ID NO: 1 of U.S. Patent 5,789,200. Thus, U.S. Patent 5,789,200 teaches polynucleotides which are the same as those of claims 6, 8, 9 and 21.

SEQ ID NO: 2 of U.S. Patent 5,789,200 (and an encoding nucleic acid sequence, SEQ ID NO: 1) comprises the amino acid sequence of SEQ ID NO: 12 (see sequence alignment) and at least 10 contiguous amino acids of SEQ ID NO: 16. In addition, U.S. Patent 5,789,200 discloses labeled oligonucleotide probes which are useful for screening cDNA, genomic DNA or mRNA libraries (column 13, lines 29-46 and column 23, lines 28-39). Oligonucleotide probes are nucleic acids that are free of dideoxynucleotides, are single stranded, may be either sense or antisense and have a label that is a radionuclide. Thus, U.S. Patent 5,789,200 teaches labeled nucleic acids which are the same as those of claims 10-14 and 22-26.

SEQ ID NO: 1 of U.S. Patent 5,789,200 also comprises a polynucleotide sequence that encodes at least 8 contiguous amino acids of a polypeptide encoded by SEQ ID NO: 1 of the instant application (see enclosed alignment). Thus, U.S. Patent 5,789,200 discloses polynucleotides which are the same as that of claim 15.

U.S. Patent 5,789,200 discloses expression and purification of an ESX transcription factor using bacteria (column 34 -36). Thus, U.S. Patent 5,789,200 disclose a transfected cell that is the same as that of claim 71.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Filloux et al (Filloux, A. et al, EMBO J., 9: 4323-4329, 1990).

Claim 1 is interpreted to be drawn to a polynucleotide that contains within the its sequence a sequence that encodes for any 5 amino acids derived from SEQ ID NO: 7 or a sequence that encodes for 5 amino acids derived from SEQ ID NO: 7 wherein any number of the 5 amino acids may be conservatively substituted.

Filloux et al teach a nucleic acid comprising a polynucleotide sequence that encodes a xcp polypeptide of *Pseudomonas aeruginosa*. Within the polynucleotide sequence of Filloux et al is a nucleotide sequence that encodes for regions of 5 amino acids (40-44) and 7 amino acids (50-56) of SEQ ID NO: 7 (see enclosed amino acid sequence alignment) wherein, for the 5 amino acid region, 3 amino acids are conservatively substituted and for the 7 amino acid region, 2 amino acids are conservatively substituted. Thus, Filloux et al teach a nucleic acid which is the same as claimed.

10. Claims 16 is rejected under 35 U.S.C. 102(b) as being anticipated by either Giovane et al (Giovane, A. et al, Genes Dev., 8: 1502-1513, 1994) or Dalton et al (Dalton, S. et al, 68: 597-612, 1992).

Claim 16 is drawn to an isolated nucleic acid comprising a nucleotide sequence encoding at least about 10 contiguous amino acids from a sequence having an amino acid sequence as set forth in SEQ ID NO: 16 or a sequence of SEQ ID NO: 16 with conservative amino acid substitutions.

Giovane et al disclose a polynucleotide sequence that encodes a polypeptide comprising 12 contiguous amino acids that are the same or have conservative amino acid substitutions as amino acids 326-337 of SEQ ID NO: 16 (see sequence alignment). Dalton et al disclose a polynucleotide sequence that encodes a polypeptide comprising 12 amino acids that are the same or have conservative substitutions as amino acids 326-337 of SEQ ID NO: 16 (see sequence alignment). Thus, either Giovane et al or Wilson et al teach nucleotide sequences which are the same as that claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Accession No. R50578, Accession No. H12657, Accession No. T27397 or Accession No. R73021 in view of Promega Corporation (Promega Protocols and Applications Guide, Promega Corporation, pages 145-153, 1991).

Claims 10-14 are drawn to nucleic acids comprising a label and a polynucleotide encoding the amino acid sequence of SEQ ID NO: 12 or an amino acid sequence of SEQ ID NO: 12 with conservative amino acid substitutions.

Accession Nos. R~~5078~~ 50578, H12657, T27397 or R73021 teach nucleic acids comprising polynucleotides encoding SEQ ID NO: 12 (enclosed are database matches between back translated amino acid sequence of SEQ ID NO: 12 and nucleic acid databases). Accession Nos. R5078, H12397, T27397 and R73021 do not teach labeled polynucleotides. However, it well known how to label polynucleotides for the purposes of making probes as disclosed by Promega Corporation. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified any one of the polynucleotides of Acession Nos. R5078, H12657, T27397 or R73021 by adding a label in order to make a probe to be used in nucleic acid detection.

12. Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,789,200.

U.S. Patent 5,789,200 discloses that polynucleotides such as that of disclosed SEQ ID NO: 1 may be employed as research reagents in polynucleotide assays (column 13, lines 47-51 and column 23, line 1 column 25, line 58). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to have assembled the

polynucleotides disclosed by U.S. Patent 5,789,200 into kits for purposes of increased marketability, convenience and reliability.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
March 28, 2000

Yvonne Eyler

YVONNE EYLER, PH.D
PRIMARY EXAMINER